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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,681	05/10/2001	Alexander James Wigmore	2001-0878.ORI	7056

7590 08/23/2004

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,681	WIGMORE, ALEXANDER JAMES	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,16,30 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,16,30 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time, Oath or Declaration, and Amendment filed 05/03/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9, 16, 30 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the disintegrants in claim 1, as well as newly added claims 34-36.

Applicant's specification at page 4 discloses from 15 to 90%, preferably from 20, 30, 40, 50, 60, 70, 80, or 90 to 95% or 100% of the chromone dissolves within 10, or preferably about 1, 2, 3, 4, 5, 6, 7, 8 or 9, or less. It appears that applicant's specification does not provide support for "at least about 27%" and "at least about 21%" of the chromone dissolves, as recited in claims 35 and 36.

Regarding claim 34, it appears that applicant's specification does not provide support for the limitation "at least about 80% of the chromone dissolves within about 5

minutes". The word "at least" set a *lower* limit of the chromone dissolves to 80%, wherein applicant's specification discloses the lower limit that can be as little as 15% (page 4). Similarly, the word "about" does not include at least 15% of the chromone dissolves.

In accordance with MPEP § 714.02, applicant should specifically point out support for any amendments made to the disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-9, 16, 30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts et al. US 6,200,602.

Watts teaches a composition for enhanced uptake of polar drugs, including sodium cromoglycate, from the colon (see abstract, column 5, lines 33-35). The composition also comprise dispersing agent (surfactant) having HLB value between 1-20 (column 4, lines 20 through column 2, lines 1-4). The composition further comprises excipient, such as Avicel™ (microcrystalline cellulose), and can be formulated into capsule, tablet or pellets (column 6, lines 16-20). The dosage form can be coated to ensure that the tablet or pellet does not break-up and release the drug until it reaches the proximal colon (column 6, lines 21 through column 7, lines 1-27).

Watts does not teach the dissolve rates of the dosage form. However, Watts teaches the use of similar coating material (enteric coating), which only begin to dissolve when the dosage form entered the small intestine (column 6, lines 45-48). "When the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established". *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Therefore, it is the position of the examiner that the enteric coated tablet or pellet of Watts would have similar dissolve rates desired by the applicant. Accordingly, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable dissolve rate to obtain the claimed invention, because Watts teaches the advantageous results in the use of similar enteric-coated dosage form to ensure the release of drug in the small intestine.

It is noted that Watts does not teach the diameter size of the pellets. However, Watts teaches similar dosage form, *e.g.*, enteric-coated pellets useful to deliver drug to the proximal colon (id). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, it is the position of the examiner that the diameter size of the pellets would have been obvious to one of the skilled artisan.

Although Watts teaches the use of microcrystalline cellulose, Watts is silent as to the amounts being used. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is

evidence indicating such concentration is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 05/03/04 have been fully considered but they are not persuasive.

Applicant argues that Watts does not teach the rapid dissolution of the composition and rapid bioavailability of the polar drug as a goal or characteristic of its composition. In fact, Watts teaches the desire of allowing the capsule to breakup only after about 3-4 hours of exposure to intestinal fluid so that the composition will eventually be released in the colon. Contrary to the applicant's argument, what Watts discloses in column 6 is the thickness of the coating that prevent the dosage form to breakup and release the chromone in the stomach, but until it reaches the colon. The 3-4 hours are the time it takes for the coating to dissolve, thereby allowing the capsule underneath to breakup (release chromone) when it has reached the terminal ileum or the colon (simulated intestinal fluid). This is also applicant's desire, see specification at page 4, lines 7-9, and page 5, lines 1-12 disclosed "...not more than 10% of the chromone dissolves after thirty minutes, one, two, *three or five hours* exposure of the composition to simulated gastric fluid".

Applicant argues that nowhere do Watts teach or suggest rapid composition dissolution in order to make the chromone bioavailable within the duodenum. Therefore, no motivation exists in the cited prior art to reach the presently claimed composition. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., rapid composition dissolution in order to make the chromone bioavailable within the duodenum) are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's attention is called to the term "proximal colon" includes the ascending and transverse regions (column 6, lines 25-27).

Applicant argues that nowhere does Watts teach or suggest the claimed ratio of disintegrant to chromone in order to achieve the unique functional characteristics of the claimed composition, wherein the ratio of the disintegrant to chromone is absolutely critical to the rapid dissolution characteristics. Such ratio criticality is described at page 17 of the specification as well as the Wigmore Declaration dated 05/29/03. In response to applicant's argument, the Declaration filed 05/29/03 has been carefully reviewed, however, it is noted that the Declaration does not show any side-by-side example between the claimed invention and those of Watts. The Declaration has not shown the dosage form taught by Watts does not have the same bioavailability as the claimed invention. Applicant's attention is called to column 8, lines 1-67, where Watts also teaches the desirability to increase drug absorption in the GI tract. Accordingly, it would

have been obvious for one of ordinary skill in the art to modify the dosage form of Watts with the expectation of at least similar result.

The 103(a) rejection over Wigmore GB 2 324 962 A has been withdrawn in view of applicant's argument regarding the foreign priority date.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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